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EXAMINER

PRATS, FRANCISCO CHANDLER

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1651 | (D) |

DATE MAILED: 04/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/915,028

Applicant(s)

SREENATH, HASSAN K.

Examiner

Francisco C Prats

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*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --***Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 04 March 2003.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-5 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-5 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.

4) Interview Summary (PTO-413) Paper No(s) _____.
5) Notice of Informal Patent Application (PTO-152)
6) Other: _____.

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DETAILED ACTION

The amendment filed March 4, 2003 (certificate of mailing February 26, 2003), has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claims 6-13 have been cancelled.

Claims 1-5 are pending and are examined on the merits.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lacoste-Bourgeacq et al (U.S. Pat. 6,042,853) in view of Etchells et al (U.S. Pat. 3,410,755).

Lacoste-Bourgeacq discloses the digestion of sausage casings, including spent sausage casings, using cellulase enzyme, whereby a solution containing monosaccharides including glucose is produced. See column 3, lines 4-12. Lacoste-

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Bourgeacq differs from claims 1-5 in that Lacoste-Bourgeacq does not disclose the fermentation of the glucose-containing sausage casing hydrolysate to lactic acid. However, the fermentation of glucose to lactic acid by the claimed microorganisms is an extremely well-known process. Etchells discloses that the claimed microorganisms were known at the time of applicant's invention to produce lactic acid from glucose. See, e.g., column 1, lines 52-59, as well Table I at column 4.

Thus, the artisan of ordinary skill, recognizing the glucose-containing cellulase-hydrolyzed sausage casing solution of Lacoste-Bourgeacq to be a suitable carbon source for the lactic acid producing microorganisms of Etchells, clearly would have been motivated to have used the glucose-containing cellulase-hydrolyzed sausage casing solution of Lacoste-Bourgeacq as a carbon source for the lactic acid producing microorganisms of Etchells. Additional motivation would have been derived from the fact that rather than simply discarding the cellulase-hydrolyzed solution of Lacoste-Bourgeacq as discussed at column 3, lines 9-11, the artisan of ordinary skill would have reasonably expected that the glucose-containing solution would have been useful as a carbon source for lactic acid producing bacteria, with minimal processing. A holding of obviousness is therefore required.

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Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lacoste-Bourgeacq et al (U.S. Pat. 6,042,853) in view of Etchells et al (U.S. Pat. 3,410,755), as applied to claims 1-4 above, and further in view of Chahal (U.S. Pat. 5,047,332), Madamwar et al (J. Ferment. Bioengineer. 67(6):424-426 (1989)), and Ono (U.S. Pat. 3,232,832).

As discussed above, when viewed in light of Etchells, Lacoste-Bourgeacq suggests the process recited in claims 1-4. Claims 4 and 5 contain embodiments requiring the cellulase enzyme to be produced by solid state fermentation (SSF) of certain microorganisms, such a process is not disclosed or suggested by Etchells and Lacoste-Bourgeacq, viewed by themselves. However, each of Chahal (*T. reesei*, column 10, line 40 through column 11, line 35) and Madamwar (*A. niger*, see whole document) discloses that it is advantageous to produce cellulase to be used in digestion of waste cellulosic materials, so as to produce glucose for use in subsequent fermentations. Thus, applicant's claimed use of SSF for producing cellulase to be used in digestion of waste cellulosic sausage casings must be considered obvious. Lastly, although Ono does not directly disclose the use of SSF to produce cellulase from *R. oryzae*, Ono makes it clear that *R. oryzae* was well known at the time of

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applicant's invention to produce cellulase. In view of the advantageousness of using SSF to produce cellulase from known cellulase-producing organisms, disclosed by Chahal and Madamwar, the artisan of ordinary skill would have been motivated to have used the methods of Chahal and Madamwar to produce cellulase from *R. oryzae*. A holding of obviousness is therefore required.

Response to Arguments

All of applicant's argument has been fully considered but is not persuasive of error. It is noted that *In re Vaeck* prohibits a holding of obviousness unless motivation for practicing the claimed subject matter is present in the art. However, it is respectfully submitted that applicant's reading of Vaeck is much too narrow. Applicant's strict reading of the language in Vaeck would effectively eliminate the doctrine of obviousness under § 103(a), because any reference that is not anticipatory could not suggest the claimed subject matter, since the only way to suggest the claimed subject matter would be to disclose it entirely. This is clearly not the state of the law. Rather, in response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based

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upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Applicant urges that the prior art does not provide motivation for treating the spent sausage casings with both the cellulase enzyme and the lactobacilli. This is clearly not the case. Using only the cited references, one of ordinary skill in the art knew that contacting spent sausage casings with cellulase results in a glucose-containing solution. The artisan of ordinary skill at the time of applicant's invention also knew that glucose was a suitable carbon source for lactobacilli, which convert the glucose to lactic acid. Thus, reasonably expecting the cellulase/sausage casing mixture to result in a suitable carbon source for lactobacilli, the artisan of ordinary skill clearly would have been motivated to include lactobacilli in the cellulase/sausage casing milieu, reasonably expecting the lactobacilli to produce lactic acid. None of the above requires any knowledge of applicant's disclosure. Thus, no improper hindsight reasoning is involved.

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With respect to the distinction urged by applicant between sausage casings and a glucose-containing cellulase-hydrolyzed sausage casing solution, it is not agreed that any such distinction exists. A glucose-containing cellulase-hydrolyzed sausage casing solution in fact contains spent sausage casings. Moreover, note specifically that applicant's claims do not recite anything about the timing of the addition of cellulase vis-à-vis the lactobacilli.

The fastidiousness of the lactobacilli, urged by applicant, is noted. However, applicant's claims recite the process in "open" comprising language. Thus applicant's claims encompass the presence in the milieu of any of the ingredients, such as buffers and minerals, disclosed in Etchells as being required for the lactobacilli to convert glucose to lactic acid.

It is also noted that the optimal temperatures for the cellulases disclosed in Lacoste-Bourgeacq are somewhat different than the optimal growth temperatures for the lactobacilli disclosed in Etchells. However, it is respectfully submitted that the active ranges of the cellulases disclosed in Lacoste-Bourgeacq sufficiently overlap the optimal growth temperatures for the lactobacilli disclosed in Etchells, such that the artisan of ordinary skill would have reasonably expected the lactobacilli of Etchells to have been able to convert the

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glucose produced in Lacoste-Bourgeacq's process to lactic acid. Note specifically that cellulase conversion does in fact occur at 40°C to 60°C. See, e.g., claim 16 of Lacoste-Bourgeacq, at column 10, lines 17-18. Note further that lactobacilli include species which grow optimally at 45°C. See Etchells at column 4, lines 30-31. Thus, contrary to applicant's argument, the lactobacilli are in fact capable of converting the glucose into lactic acid at the same temperatures the cellulases convert cellulose in glucose. In this regard it is further noted that applicant's claims do not recite any sort of temperature limitation.

It is also noted that applicant urges that spent casings contain large amounts of salt nitrate and nitrite, which applicant urges would have been expected to have inhibited the growth of the microorganisms. However, applicant has not supported this assertion by any factual evidence. Moreover, applicant's claims do not contain any language excluding process steps whereby these alleged inhibitory substances are removed from the casings, for example by washing. Thus, applicant's claims do not reflect the alleged differences over the prior art.

Lastly, applicant's argument regarding the improvement with respect to conversion of cellulose to glucose resulting from the

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presence of the lactobacilli, thereby alleviating the problem of feedback inhibition, has been noted. However, note specifically that Figure 1 depicts this improvement with respect to simultaneous saccharification and fermentation of glucose to ethanol, not to lactic acid, as recited in the claims under examination. For the sake of argument it can be assumed that this improvement occurs in processes of simultaneous saccharification/fermentation to lactic acid. However, it is respectfully pointed out that the processes disclosed in the specification whereby improved cellulose conversion occurs contain numerous process parameters, none of which are recited in the claims under examination. Rather, the claims under examination recite virtually no process conditions or parameters, thereby encompassing the very processes argued by applicant as being inferior. Thus, even if some unexpected result were considered to come from some process disclosed by applicant, the present claims' entire lack of process parameters means that the claims are not commensurate in scope with any showing of such an unexpected result. See MPEP § 716.02(d).

In sum, contrary to applicant's argument, the artisan of ordinary skill would have reasonably expected the lactobacilli of Etchells to have been able to convert the glucose produced in Lacoste-Bourgeacq's process to lactic acid. Thus, the artisan

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of ordinary skill would have been motivated to have included Etchells' lactobacilli in the cellulase/sausage casing milieu of Lacoste-Bourgeacq, so as to produce lactic acid via the conversion of the glucose produced by Lacoste-Bourgeacq's cellulase. The obviousness rejection must therefore be maintained.

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C Prats whose telephone number is 703-308-3665. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Francisco C Prats
Primary Examiner
Art Unit 1651

FCP
April 21, 2003